

REMARKS

Introduction

Applicants have amended claim 1, deleting fragment language as it refers to SEQ ID NO:24. Applicants have also amended claims 54, and 56-58 to indicate that the claimed progeny, plant, meiocyte, gamete, ovule, pollen or endosperm, seed, embryo or propagule, comprises the minichromosome of claim 1. Bases for these amendments can be found in claim 1 as filed, and in the specification at, among others, page 8, line 21 to page 9, line 3. The amendment to claim 61 corrects a typographical error. Applicants have cancelled no subject matter related to patentability, including for reasons of enablement or written description; all amendments have been made without prejudice to pursuing any deleted subject matter in this or a continuing application. No new matter has been added as a result of these amendments. Applicants respectfully request entry of the amendments into the claims.

Claims 1-3, 7, 10, 11, 14-16, 19, 25, 30, 39, 43-46, 54, 56-62, 66, 89, 90, 93, and 96 are pending.

Applicants thank the Examiner for withdrawing rejections under 35 USC 112, 2nd paragraph, 35 USC 102, 35 USC 103 and the previous double patenting rejections.

The rejection under 35 USC 112, 1st paragraph (enablement) should be withdrawn: the claims are fully enabled

Applicants respectfully request the Office to withdraw its rejection under 35 USC 112, 1st paragraph (enablement). The amended claims are fully enabled by the specification as filed.

The Office has cited Tek *et al.* (*Chromosome Research* 18:337-347, 2010) ("Tek") as evidence that the instant application is non-enabled because Office avers that Tek. shows that GmCent-1 and GmCent-2 repeats are necessary for centromere function. Applicants

respectfully traverse because Tek did not show that the centromeric sequences Tek identified *are required* for centromere function.

The Office cited Tek as evidence that the location of a sequence in the centromeric region is not sufficient to confer centromere function and to demonstrate that more than one type of sequence that interacts with histones (CENH3) may be necessary for kinetochore function in soybeans. However, the studies in Tek did not test the ability of the identified sequences to segregate to daughter cells during cell division and instead relied on ChIP experiments using CENH3 combined with FISH and sequence analysis to demonstrate the localization of sequence to the centromeric region. The Office acknowledges that merely identifying sequences that react with CENH3 does not appear to be sufficient to give guidance to the sequences that confer centromeric function (Office Action of December 23, 2010; page 5, last paragraph to page 6). Thus, the teachings in Tek do not support the Office's assertion that the pending claims are not enabled by the specification. Contrary to the teaching in Tek, Applicants have not relied on CENH3 as the key to centromeric function, but instead, have used functional assays that demonstrate that the presently claimed invention is fully enabled. In working Example 10 of the specification as filed (paragraphs [0432] to [0448]; citations are to the published application, US Publication No. 20080060093), Applicants demonstrated that a mini-chromosome derived from BAC SB12 comprising SEQ ID NO:24 was retained as an autonomous, circular mini-chromosome in transgenic soybean cells that had been propagated for 5 months (paragraph [0444]). Applicants demonstrated that this mini-chromosome was autonomous by two independent criteria: (1) mini-chromosome rescue (paragraphs [0444] to [0445]), and (2) FISH analysis (paragraph [0446]). In the rescue experiments, antibiotic-resistant (a trait carried on the mini-chromosome construct and not native to the soybean genome) colonies were observed from DNA extracted from cells treated and untreated with exonuclease (linear DNA is susceptible to exonuclease, while circular DNA is resistant), but no antibiotic resistant colonies were observed in exonuclease-treated controls (paragraph [0444]). In FISH analysis, Applicants observed staining of an autonomous, circular mini-chromosome and in the same line, no integrated copies of the construct into the native genome. Centromere staining was also observed. Applicants also sequenced two

mini-chromosomes, one derived from the SB12 BAC used in the autonomy analyses, and SB6 (paragraphs [0447] to [0448]). This sequence analysis demonstrated that in the SB12-derived mini-chromosome 80% of the insert was composed of tandem satellite repeats, 9.9% made up of retroelement-related sequences, and 10.1% representing novel, contiguous sequence (paragraph [0448]). All of the results provided in Example 10 demonstrate that the invention as presently claimed, is fully enabled.

Applicants also note that the Office has mis-applied a post-filing reference in its enablement rejection, for which the *MPEP* gives clear guidance. "In general, the examiner should not use post-filing date references to demonstrate that the patent is non-enabling. Exceptions to this rule could occur if a later-dated reference provides evidence of what one skilled in the art would have known on or before the effective filing date of the patent application. *In re Hogan*, 559 F.2d 595, 605, 194 USPQ 527, 537 (CCPA 1977) Tek does not show what was not known at the time of filing or that the invention, as presently claimed, does not work. Tek shows, at best, that the GmCent-4 repeats can be found in centromeric regions, but did not state that both GmCent-1 and GmCent-4 repeats are *necessary* for centromere function. In fact, Tek makes no assertion about the ability of any of the identified sequences to function together or individually as centromere sequences. Tek does *not* state that the present invention as claimed was not possible at the time the present application was filed. Tek is simply unable to do so because Tek does not describe any experiments where the identified sequences were tested for their ability to segregate to daughter cells during cell division. Applicants, however, have performed such experiments, as discussed above. Nowhere does Tek say that all the identified sequences are, or any particular sequence is, essential for soybean centromere function. Thus, the Office's reliance on the teachings in Tek to support the rejection for lack of enablement is improper. The pending claims are enabled by the specification for the reasons set out above and in the previous response, therefore the rejection under 35 USC 112, first paragraph for lack of enablement should be withdrawn.

The rejection under 35 USC 112 – written description should be withdrawn: the amended claims are fully described in the specification

The Office is respectfully requested to withdraw the rejections under 35 USC 112 – written description because (1) Applicants' amendment obviates in part the rejection in deleting the alternative of a fragment of SEQ ID NO:24; and (2) Applicants have fully described functional centromere sequences throughout the specification, and in the case of SEQ ID NO:24, Example 10 as discussed above.

As noted above, Applicants fully described and produced autonomous, circular mini-chromosomes comprising SEQ ID NO:24 (thus defining the invention by its physical and chemical properties as required by, for example, *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d, 1016 at 1021, (Fed Cir. 1991)) as shown in Example 10 - contrary to the Office's assertion that Applicants have not produced any such working examples.

The Office appears to be relying on the post-filing art of Tek in asserting that the specification does not described all the necessary sequence for centromere function and does not describe what is necessary for the claimed function. Tek did not test any centromeric sequences for the ability to segregate to daughter cells during cell division. As the Office noted, "merely identifying sequences that react with CENH3, in light of the art above [referring to Tek], does not appear to be sufficient to give guidance as to sequences that confer centromeric function" (Office Action of December 23, 2010, page 5, last paragraph to page 6). Tek identified centromeric sequences by their ability to interact with CENH3, uncoupled with any functional assay that tests centromere function.

In view of the teachings in working Example 10, the specification clearly describes the necessary structural features for conferring the ability to segregate to daughter cells. Therefore, the rejection under 35 USC 112, first paragraph for lack of adequate written description should be withdrawn.

The rejection under 35 USC 101 should be withdrawn: the amended claims claim statutory subject matter

The Office is respectfully requested to withdraw the rejections under 35 USC 101 because Applicants' amendment obviates the rejection. The claims now recite that the seeds, parts, propagules and progeny comprise the mini-chromosome referred to in claim 1. Applicants thank the Examiner for the suggestion.

CONCLUSION

Applicants respectfully request timely allowance of the pending claims. Should the Office feel that there are any issues outstanding after consideration of the response; the Office is invited to contact the Applicant's undersigned representative to expedite prosecution.

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